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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,824	11/07/2001	Fernand Labrie	P/1259-636	4181

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EXAMINER

JIANG, SHAOJIA A

ART UNIT PAPER NUMBER

1617

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/052,824

Applicant(s)

LABRIE, FERNAND

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 7-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 13-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 and 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation of Serial No. 09771180 which claims priority to provisional application Serial No. 60/178601.

Applicant's preliminary amendment and response to the Restriction Requirement (see below) filed on April 30, 2002 in Paper No. 4 is acknowledged wherein claims 27-28 are newly submitted. Currently, claims 1-28 are pending in this application.

Election/Restrictions

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention: a plurality of disclosed patentably distinct compounds in the claims, e.g., claims 1-2.

Applicant is required under 35 U.S.C. 121 to elect a composition comprising a specified combination of individual compounds employed in the instant claimed method for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-11 and 13-23 are generic to a plurality of disclosed patentably distinct species (compounds). The claims 1-11 and 13-23 read on the employment of various compounds of with great diversity of chemical structure classified across class 514, the search for all of which presents an undue burden on the Office. It is noted that a reference to one combination of individual agents would not be a reference to another combination of individual agents under 35 U.S.C.103.

A "specie" is a specific compound and a specific disease or condition to be treated, with all parameters and/or substituent variables FULLY accounted for.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. Charles C. Achkar on April 29, 2002 regarding the Election of Species Requirement above, the examiner was informed that a election will be faxed to her (see below).

Applicant's election without traverse of the species of EM-652.HCl in claim 17 for the SERM compound, 17 β -estradiol in claim 20 for as an estrogen, and dehydroepiandrosterone (DHEA) for additional agent in claim 2, in Paper No. 4 submitted April 30, 2002 is acknowledged.

Claims 7-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

The claims have been examined insofar as they read on the elected specie.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 6, and 13-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "an androgenic agent" in claim 3 renders claim 3 indefinite as failing to clearly set forth the metes and bounds of the patent protection desired. Therefore, the scope of claims is indefinite as to the composition encompassed thereby.

The expressions " R100 is a bivalent moiety....B-ring by.." in claim 13 render claims 13-19 indefinite. The expressions " R100 is a bivalent moiety....B-ring by.." are not understood since "R100" is not recognized as to a chemical moiety and there is insufficient antecedent basis for the limitation, B-ring, in the claim.

Art Unit: 1617

Claims 6 and 17 contain the trademark/trade name for example HMR3339, EM-800, and EM-1520. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe particular SERM herein and, accordingly, the identification/description is indefinite.

Applicant is suggested to delete "EM-800, EM-1520..." in claim 17 since the chemical structures themselves clearly define particular compounds of SERM in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 13-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Labrie (5,362,720, PTO-1449 submitted November 7, 2001), and Labrie (5,550,107, PTO-1449 submitted November 7, 2001), and Labrie et al. (WO 96/26201, PTO-1449 submitted November 7, 2001), and Applicant's admission regarding the prior art in the specification at 2 lines 3-4.

Labrie (5,362,720) teaches that estrogens such as 17β -estradiol are well known to be used in estrogen therapy in menopausal women. However, estrogens are known to induce estrogen-dependent diseases such as breast cancer. Labrie also discloses that androgenic compounds or androgenic steroids are useful in methods of treating or preventing estrogen-dependent diseases such as breast cancer. See abstract, col.1, col.4 lines 45-48, col.10, and claims 1-30.

Labrie (5,550,107) teaches that estrogens such as 17β -estradiol and DEHA is capable to inhibiting breast tumor or cancer growth, and are therefore useful in methods of treating or preventing estrogen-dependent diseases such as breast cancer. See abstract, col.6. lines 36-44 and col.9 lines 42-53.

Labrie et al. (WO 96/26201) discloses that the particular SERM, EM-652 (the instant elected species) or its pharmaceutically acceptable salts such as EM-652.HCl, have anti-estrogen activities and are therefore useful in methods of treating estrogen sensitive or estrogen-dependent diseases such as breast cancer, which is known estrogen-induced effects. See abstract, page 1, page 6-8, 10, and 19-21, and claims 11-12.

Art Unit: 1617

Applicant's admission regarding the prior art in the specification at 2 lines 3-4 teaches that Hormone Replace Therapy (e.g., administration of estrogens) is known to be useful in treatment of menopausal symptoms.

The prior art does not expressly disclose the employment of the combination of an estrogen such as 17β -estradiol and the particular SERM, EM-652.HCl, or further combining with DHEA or maybe further combining an androgenic compound in a method of reducing or eliminating the incidence of menopausal symptoms.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ of the combination of an estrogen such as 17β -estradiol and the particular SERM, EM-652.HCl, or to further combine with DHEA, or to further combine an androgenic compound in a method of reducing or eliminating the incidence of menopausal symptoms.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the combination of an estrogen such as 17β -estradiol and the particular SERM, EM-652.HCl, or to further combine with DHEA, or to further combine an androgenic compound in a method of reducing or eliminating the incidence of menopausal symptoms, since estrogens such as 17β -estradiol and DHEA are well known in the art to be used in estrogen therapy or Hormone Replace Therapy in menopausal women for reducing or eliminating the incidence of menopausal symptoms. Moreover, 17β -estradiol and DHEA are known to be capable to inhibiting breast tumor or cancer growth, and are therefore useful in methods of treating estrogen-dependent diseases, e.g., breast cancer according to Labrie. Androgenic compounds are also

Art Unit: 1617

known to be useful in methods of treating estrogen-dependent diseases. Further, the particular SERM, EM-652.HCl, is known to be in methods of treating estrogen-dependent diseases. Therefore, one of ordinary skill in the art would have reasonably expected that combining an estrogen such as 17β -estradiol and the particular SERM, EM-652.HCl, or further combining with DHEA, or further combining an androgenic compound would be useful in reducing or eliminating the incidence of menopausal symptoms, while reducing the risk of or treating estrogen-dependent diseases such as breast cancer induced by estrogens during estrogen therapy in menopausal women for reducing or eliminating the incidence of menopausal symptoms, since each of components herein is known to be useful in the same treatment, i.e., treating estrogen-dependent diseases.

Since all active composition components herein are known to useful to reduce or treat estrogen-dependent diseases, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Art Unit: 1617

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
May 14, 2002

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